Citation:

Han JR, Deng B, Sun J, Chen CG, Corkey BE, Kirkland JL, Ma J, Guo W. Effects of dietary medium-chain triglyceride on weight loss and insulin sensitivity in a group of moderately overweight free-living type 2 diabetic Chinese subjects. *Metabolism.* 2007 Jul;56(7):985-91.

PubMed ID: 17570262

Study Design:

Randomized Controlled Trial

Class:

A - Click here for explanation of classification scheme.

Research Design and Implementation Rating:

POSITIVE: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

To test how medium chain triglyceride (MCT) affects body weight, insulin sensitivity and serum lipid profile when administered at a moderate dosage to free-living moderately overweight type 2 diabetic urban residents in China.

Inclusion Criteria:

Forty subjects (8 males and 32 females) were recruited from 2 urban hospitals' outpatient departments meeting the following criteria:

- 5-10 year history of type 2 diabetes mellitus
- 45-65 years old
- Stable body weight over the last 3 months
- Currently not taking insulin
- Regular dietary habits, rarely eat outside the home
- No cardiovascular, gastric, kidney or other systemic disease
- Normal thyroid function
- No hypertension
- Resident of an urban area of Guangzhou (the largest city in South China)

Exclusion Criteria:

- Diagnosed with type 2 diabetes mellitus for less than 5 years or greater than 10 years
- Age less than 45 years old or greater than 65 years old
- Body weight change in the past 3 months
- Using insulin
- Frequently consumes meals prepared outside of the home
- Diagnosis of cardiovascular, gastric, kidney or other systemic disease

- Abnormal thyroid function
- Hypertension

Description of Study Protocol:

Recruitment

Forty subjects were recruited from 2 urban hospitals' outpatient departments.

Design: Randomized controlled trial

Blinding used (if applicable)

Subjects were blinded to the nature of the oil they were asked to consume.

Intervention (if applicable)

- Subjects were split into 2 test groups and provided with 18g/day of a test oil (either medium chain triglyceride oil or corn oil rich in long chain triglyceride).
- No additional dietary restriction was recommended.
- Subjects were instructed not to change the food components of their diet throughout the 90-day trial period.
- Biweekly telephone interviews were conducted to measure compliance to the test protocol.

Statistical Analysis

- For baseline results, differences between groups were assessed using independent samples t test
- Changes of the outcomes within the same group were analyzed by repeated measures in the general linear model
- Differences between groups at the same point were assessed using analysis of covariance and Tukey post hoc test was applied

Data Collection Summary:

Timing of Measurements

- A food consumption survey was conducted for 3 days during the first week of the trial. Biweekly telephone interviews were conducted to measure compliance to the test protocol. The food survey was repeated at the end of the 90-day trial period
- Body weight and waist circumference were measured on days 0, 45 and 90
- Fasting blood samples were taken on days 0, 45 and 90 for glucose, insulin, triglycerides, cholesterol, low-density lipoprotein cholesterol (LDL-C), high-density lipoprotein cholesterol (HDL-C), apolipoprotein (apo) A, apo B and C-peptide
- Insulin sensitivity was evaluated based on fasting glucose and fasting insulin concentrations using the homeostasis model assessment of insulin resistance (HOMA-IR)

Dependent Variables

- Body weight
- Waist circumference
- Glucose, insulin, triglycerides, total cholesterol, LDL-C, HDL-C, apo A, apo B and

C-peptide levels
- Insulin sensitivity

Independent Variables

- Consumption of 18 g/day of a MCT oil or corn oil

Control Variables

- Food consumption and energy content of diet

Description of Actual Data Sample:

Initial N: 40 subjects (8 males and 32 females)

Attrition (final N): All subjects completed the study

Age: 45-65 years

Ethnicity: Not reported (all subjects were residents of an urban area of Guangzhou)

Other relevant demographics: Not reported

Anthropometrics At baseline, the test groups were not significantly different with regard to body weight, waist circumference or BMI distribution

Location: Guangzhou, China (South China)

Summary of Results:

Key Findings:

- The subject consuming an MCT diet showed a significant decrease in body weight and waist circumference across time ($P<0.05$); body weight and waist circumference were also significantly lower in the MCT group than the LCT group on days 45 and 90 of the trial ($P<0.05$)
- A decrease in insulin resistance (measured by homeostatic model assessment) was found in the MCT group between 45 and 90 days ($P<0.05$); insulin resistance was lower in the MCT group than the LCT group at day 90 ($P<0.05$)
- C-peptide levels increased in the MCT group from day 0 to day 90 of the trial ($P<0.05$). No change in C-peptide level was noted in the LCT group and no between group differences in C-peptide level was noted.
- A gradual decrease in total blood cholesterol, LDL-C and HDL-C was noted in the MCT group across time, but the difference only reached significance at day 90 ($P<0.05$)
- Total energy intake was decreased in the MCT group and increased in the LCT group after the 90-day intervention ($P<0.05$)
- Total energy intake and fat-derived energy intake was lower in the MCT group than the LCT group at the conclusion of the 90-day intervention ($P<0.05$)
- Dietary cholesterol intake was lower in the MCT group than the LCT group at the conclusion of the 90-day intervention ($P<0.05$)

Dietary intervention and changes in body weight, waist circumference, fasting glucose,

insulin and blood lipid profiles:

Variable	MCT day 0	MCT day 45	MCT day 90	LCT day 0	LCT day 45	LCT day 90
Weight (kg)	60.02 ± 11.48[a]	58.61 ± 10.17[b*]	58.46 ± 10.07[b*]	61.69 ± 10.66	62.19 ± 10.62[*]	61.97 ± 10.16[*]
Waist circumference (cm)	81.28 ± 9.55[a]	80.45 ± 7.90[*]	79.45 ± 8.47[b*]	84.55 ± 9.82	85.50 ± 9.05[*]	85.90 ± 8.10[*]
Glucose (mmol/L)	8.17 ± 2.22	7.98 ± 1.51	7.77 ± 2.11	7.84 ± 1.51	7.46 ± 1.25	7.47 ± 1.28
Insulin (mmol/L)	7.61 ± 6.61	8.05 ± 4.91	6.68 ± 4.27	10.62 ± 8.92	9.95 ± 4.60	10.32 ± 5.15
C-peptide (mmol/L)	0.46 ± 0.29[a]	0.52 ± 0.23	0.58 ± 0.23[b]	0.60 ± 0.27	0.59 ± 0.28	0.58 ± 0.23
Insulin resistance	2.71 ± 2.60	2.84 ± 2.00[a]	2.25 ± 1.61[b*]	3.14 ± 1.54	3.33 ± 1.63	3.37 ± 1.73[*]
Triglyceride (mmol/L)	2.42 ± 1.79	2.27 ± 1.25	2.24 ± 1.14	2.33 ± 1.31	2.07 ± 0.86	2.42 ± 1.37
Cholesterol (mmol/L)	5.89 ± 1.20[a]	5.72 ± 0.97[a]	5.20 ± 1.02[b]	5.63 ± 1.27	5.48 ± 1.20	5.60 ± 1.32
LDL-C (mmol/L)	3.44 ± 0.95[a]	3.39 ± 0.74[a]	2.87 ± 0.68[b]	3.00 ± 0.87	3.00 ± 1.08	3.10 ± 0.93
HDL-C (mmol/L)	1.44 ± 0.29[a]	1.39 ± 0.28[a]	1.21 ± 0.26[b]	1.24 ± 0.47	1.41 ± 0.37	1.35 ± 0.38
Apo A (mmol/L)	1.29 ± 0.17	1.23 ± 0.15	1.24 ± 0.17	1.24 ± 0.22	1.24 ± 0.18	1.28 ± 0.22
Apo B (mmol/L)	1.12 ± 0.24	1.10 ± 0.21	1.03 ± 0.22	1.04 ± 0.41	0.97 ± 0.32	0.97 ± 0.28

[a,b] within-group comparison (P<0.05, repeated measures)
[*] same time point between-group comparison (P<0.05, ANOVA)

Author Conclusion:

- Compared with LCT, consumption of a moderate amount of MCT correlates with a spontaneous reduction in total energy intake, body weight and waist circumference
- The subjects in the study consumed diet lower in fat content (23-24% of energy derived from fat) than the average Western diet would provide (40% of energy derived from fat)
- The protocol implemented provided a low-cost, feasible way to provide MCT to free-living human subjects
- The study focused on a group of overweight, middle-aged, type 2 diabetic in an urban setting. The results suggest that this population could benefit from long-term consumption of a moderate dose of MCT in a free-living environment

Reviewer Comments:

- *The population studied was limited to moderately overweight, middle-aged, type 2 diabetic, urban residents. Results should not be extrapolated to the population as a whole*
- *The use of blinding in the intervention trial was not clear. The authors made it clear that the study subjects were blinded to treatment group, but it is unclear whether the clinicians and investigator were also blinded to treatment group*
- *No adjustments were made in the statistical analysis for potential confounding factors such as decreased energy intake*

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions		
1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)	Yes
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes

Validity Questions		
1.	**Was the research question clearly stated?**	Yes
1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes
1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes
1.3.	Were the target population and setting specified?	Yes
2.	**Was the selection of study subjects/patients free from bias?**	Yes
2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes
2.2.	Were criteria applied equally to all study groups?	Yes
2.3.	Were health, demographics, and other characteristics of subjects described?	Yes

2.4.	Were the subjects/patients a representative sample of the relevant population?	Yes
3.	**Were study groups comparable?**	Yes
3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	Yes
3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	Yes
3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	Yes
3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	N/A
3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A
3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	**Was method of handling withdrawals described?**	Yes
4.1.	Were follow-up methods described and the same for all groups?	Yes
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	Yes
4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
4.4.	Were reasons for withdrawals similar across groups?	N/A
4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
5.	**Was blinding used to prevent introduction of bias?**	Yes
5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	Yes
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	Yes
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	N/A

5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.	**Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were interveningfactors described?**	Yes
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	Yes
6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	N/A
6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	Yes
6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	Yes
6.6.	Were extra or unplanned treatments described?	N/A
6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	Yes
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	**Were outcomes clearly defined and the measurements valid and reliable?**	Yes
7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes
7.5.	Was the measurement of effect at an appropriate level of precision?	Yes
7.6.	Were other factors accounted for (measured) that could affect outcomes?	Yes
7.7.	Were the measurements conducted consistently across groups?	Yes
8.	**Was the statistical analysis appropriate for the study design and type of outcome indicators?**	Yes
8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes

	8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
	8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
	8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	N/A
	8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	No
	8.6.	Was clinical significance as well as statistical significance reported?	Yes
	8.7.	If negative findings, was a power calculation reported to address type 2 error?	Yes
9.	**Are conclusions supported by results with biases and limitations taken into consideration?**		Yes
	9.1.	Is there a discussion of findings?	Yes
	9.2.	Are biases and study limitations identified and discussed?	Yes
10.	**Is bias due to study's funding or sponsorship unlikely?**		Yes
	10.1.	Were sources of funding and investigators' affiliations described?	Yes
	10.2.	Was the study free from apparent conflict of interest?	Yes